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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,930

09/20/2005

Maria Alessandra Alisi

278220US0PCT

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08/25/2008

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.  
1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER

CHANG, CELIA C

ART UNIT

PAPER NUMBER

1625

NOTIFICATION DATE

DELIVERY MODE

08/25/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com  
oblonpat@oblon.com  
jgardner@oblon.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/549,930	<b>Applicant(s)</b> ALISI ET AL.	
	<b>Examiner</b> Celia Chang	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 33-35 is/are pending in the application.
- 4a) Of the above claim(s) 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28, 31, 33-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### DETAILED ACTION

1. Applicant's election with traverse of group I, claims 1-22 and 31 in the reply filed on Jun.13, 2008 is acknowledged. The traversal is on the ground that there is no burden in searching all the groups. This is not found persuasive because it was clearly delineated the restriction was based on independent and non-coextensive subject matter. Applicants were advised that :

*"Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.*

In the instant case, then, there would have been no patentability of all the claims over Gong et al. US 6,770,650, see col. 40, formula IIc encompassed claim 30.

The requirement is still deemed proper and is therefore made FINAL.

Per applicants request, the alternative method of making compounds of group I would be searched, thus, groups I-III are rejoined and the restriction among these groups are withdrawn.

Claim 32 has been canceled. Claim 30 is withdrawn from consideration per 37 CFR 1.142(b). Claims 1-29, 31, and 33-35 are prosecuted.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

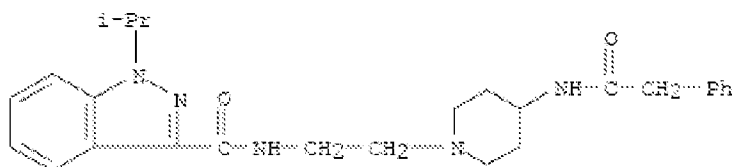
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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-29, 31, and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Catlow et al. US 5,654,320 in view of Suzuki et al US 6,096,746 and Schaus et al.

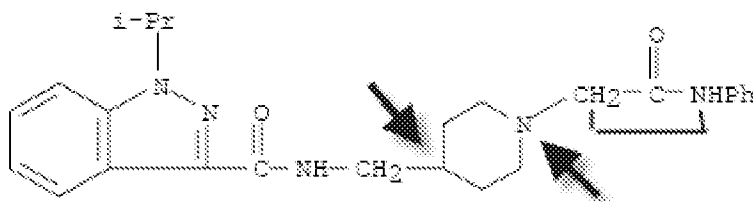
Determination of the scope and content of the prior art (MPEP §2141.01)

Catlow et al. '320 disclosed 5HT<sub>4</sub> receptor binding compounds for treating gastrointestinal disorder and a species which is structurally very close to the claims is see at col. 14, example 26:



Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between this compound and the species of instant claim 8 :



is the one methylene linker between the indazolyl and the piperidiny ring, the rotation of the piperidiny ring and the reverse amidomethyl linkage.

Suzuki et al. taught that the one methylene linker difference is an optional choice for such compounds, see col 54-55 examples 18 and example 19. Schaus et al. taught that the class of 5HT<sub>4</sub> receptor binding compounds can have the piperidiny ring being linked at the N or C i.e. ring rotation, as an optional choice see p.1948 table 3 vs p.1950 table 5. Schaus et al. also taught that the reverse amidomethyl linker is an optional choice for such compounds, see p.1948 compound 19j vs p.1950 compound 23j, both have potent binding activity (see p.1948 right column last 4 lines and p.1951 right column 2<sup>nd</sup> paragraph last 10 lines).

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art is deemed to be aware of all the pertinent art in the field. The above exemplified compounds are active. The modification of one proven compound with attributes of another proven compound is prima facie structural obvious since one having ordinary skill is given suggestion to employ the particular structural feature which was proven successful in binding activity. In addition, the Schaus et al. reference also provided variations in substitution on the terminal phenyl ring i.e. the R<sup>3</sup> or R<sup>4</sup> elements (see Schaus et al. p.1944), thus, rendered the scope of the instant claims being drawn to substituted phenyl prima facie obvious over the art. In absence of unexpected results, the mere picking and choosing the well

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suggested attributes of the successful compounds of the prima art is prima facie obvious **because** the indazolyl-linker-piperidinyl-linker-phenyl scaffold has been established for 5HT4 receptor and the tolerance of linker length, ring variation and substituents have also been well correlated with the binding activity (see Schaus et al. whole article). The teaching, suggestion and motivation for one skilled in the art to pick and choose the known attributes among the successful compounds is prima facie obvious design choice.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang*  
*Aug. 19, 2008*

*/Celia Chang/*  
*Primary Examiner*  
*Art Unit 1625*